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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,751	11/16/2001	David G. Charne	1311	8260
27310	7590	01/16/2004	EXAMINER	
PIONEER HI-BRED INTERNATIONAL INC. 7100 N.W. 62ND AVENUE P.O. BOX 1000 JOHNSTON, IA 50131			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/993,751	Applicant(s) CHARNE ET AL.	
	Examiner David H Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15,22-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 22-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the Amendment and Remarks filed 29 October 2003.
2. Applicant's confirmation of the Election of Group I, claims 1-15, without traverse to the Restriction requirement outlined in the previous Office action is noted (pages 9-10 of the Remarks).
3. The Information Disclosure Statement filed 10 October 2003 has been considered, a signed copy is attached to this Office action.
4. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d) on 10 November 2003, which papers have been placed of record in the file. Applicant has perfected the claim of Foreign Priority.
5. Those rejections or objections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

7. The Specification is objected to. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication, as claimed on page 1 of the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same

Art Unit: 1638

material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejections - 35 USC § 112

8. Claim 8 remains rejected and new claims 22-34 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 30 July 2003. Applicant's arguments filed 29 October 2003 have been fully considered but they are not persuasive.

Applicant claims a method of breeding a *Brassica* line comprising crossing the exemplified NS2313 line with a second *Brassica* plant. At claim 8, the method of breeding is further defined as selected from method such as pedigree breeding and backcrossing. Applicant also claims progeny of the exemplified NS2313 *Brassica napus* line.

Applicant describes *Brassica* line NS2313 that exhibits an "R" rating for blackleg and resistance to at least one AHAS-inhibitor.

Applicant does not describe the genus of progeny plants descended from NS2313 or those progeny or descendants that would be required to practice the claimed method of breeding as broadly claimed.

Art Unit: 1638

The claimed invention lacks adequate written description under current written description guidelines. The claims are drawn to *Brassica* progeny plants having undisclosed identifying characteristics and a method of using said progeny plants, whereby only the characteristics of the *Brassica* line NS2313 are known. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the plant obtained at each level of crossing or at each generation. Over an undetermined number of generations, the identifying characteristics of each generation become highly unpredictable, especially in view of the fact that none of the identifying characteristics of the progeny plants are disclosed in the specification. Furthermore, neither the individual traits themselves, nor their degree of expression, appear to be unique to the *Brassica* line NS2313, in particular having an "R" rating for blackleg and resistance to at least one AHAS-inhibitor herbicide, both characteristics known to be associated with other *Brassica napus* plants. Accordingly, there is a lack of adequate description of the claimed progeny plants and method of using progeny, in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. Hence, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday 5, 2001/ Notices; p. 1099-1111).

Applicant argues that the rejection has been overcome in view of Applicant's amendment to claim 7 reciting said progeny have at least partial tolerance to at least on

Art Unit: 1638

AHAS-inhibitor herbicide and at least the AHAS1 mutation is inherited from the exemplified NS3213 plant (page 11 of the Remarks). This argument is not found to be persuasive as directed to claim 8, because this claim is directed to a method of using progeny of the exemplified NS3213 *Brassica* plant in additional breeding steps. As such, Applicant has failed to adequately describe such progeny plants required to practice the claimed method. In addition, Applicant does not describe the AHAS1 mutation in the exemplified NS3213 *Brassica* plant or how to distinguish progeny from other *Brassica* plants comprising an AHAS1 mutation inherited from *Brassica* line 45A71, that confers at least partial tolerance to at least on AHAS-inhibitor herbicide as broadly claimed (see page 24 of the specification for a description of the pedigree of the exemplified NS3213 *Brassica* line).

9. Claims 1-15 remain rejected and new claims 22-34 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 30 July 2003. Applicant's arguments filed 29 October 2003 have been fully considered but they are not persuasive.

The rejection of claim 8 as lacking adequate enablement as outlined in the previous office action remains for the reason of record. The Examiner has addressed this issue in the above rejection (page 12, 1st paragraph of the Remarks).

Art Unit: 1638

The issue of enablement as directed to the Deposit of Biological Material remains for the reason of record. Applicant has supplied a Deposit Statement in the response filed 29 October 2003. Applicant's response does not address the issue of under what conditions the Deposit of Biological Materials has been made. See 37 CFR §§ 1.801-1.809 and the previous Office action.

New claims 22-34 lack adequate enablement because they are directed to a myriad of progeny *Brassica* plants which Applicant has failed to teach one of skill in the art how to make and use within the meaning of 35 U.S.C. § 112, first paragraph.

The teachings of *In re Wands* (1988) can be found in the previous Office action.

See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC § 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

In the instant case, Applicant provides no guidance on how the exemplified NS3213 *Brassica napus* plant will recombine with other *Brassica* plants to produce useable progeny. The art teaches that a canola cultivar needs to be homogenous,

Art Unit: 1638

homozygous and reproducible to be useful for the production of a commercial crop on a reliable basis (Patel, U.S. Patent 6,288,307, column 7, lines 66-68). In addition, the art teaches that the inheritance of blackleg resistance in *Brassica napus* is complex and not completely predictable because different loci that control different types of resistance reside in different genomes (Pang *et al* 1996, Theor. Appl. Genet. 92:382-387, see especially page 386). As such, one of skill in the art would have to determine what other *Brassica* line(s) would recombine in a useful way with the exemplified NS3213 *Brassica napus* line, select useful progeny and then stabilize the segregating population of progeny plants to produce a useful cultivar. It is the Examiner's opinion that given the limited guidance by Applicant for making and using progeny of the exemplified NS3213 *Brassica napus* line, the unpredictability of how two *Brassica* plants will recombine without trial and error experimentation, and the teaching of the art as to what constitutes a useful *Brassica* line, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention.

At claims 27-30, the claimed *Brassica juncea* plant descendant from a cross between the exemplified NS3213 variety and a second *Brassica* plant wherein said *Brassica juncea* plant has full tolerance to at least one AHAS-inhibitor herbicide and wherein both the AHAS1 mutation and the AHAS3 mutation are inherited from said NS3213 variety is not enabled. In the instant case, Applicant states that the AHAS1 mutation is located on the C genome and the AHAS3 mutation is located on the A genome (page 3, last paragraph of the specification). It is well known in the art at the time of Applicant's invention that *Brassica napus* as exemplified by variety NS3213

Art Unit: 1638

comprises an A genome and a C genome, while *Brassica juncea* comprises an A genome and a B genome. Therefore, the AHAS1 mutation would have to be present on the A genome for one of skill in the art to produce the claimed *Brassica juncea*.

Applicant provides no guidance on how one of skill in the art can predictably move the AHAS1 mutation from the C genome to the A genome in order to produce the claimed *Brassica juncea* plant without undue trial and error experimentation, as recombination of *Brassica* sp. genomes in interspecies crosses are random and highly unpredictable.

10. Claims 22-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-30 are indefinite because the sole designation of a plant by its breeding line name or number is arbitrary and creates ambiguity in the claims, in the instant case "variety NS3213". For example, the plant disclosed in this application could be designated by some other arbitrary means, or the assignment of the breeding line name could be arbitrarily changed to designate another plant. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to the deposit accession number of the claimed breeding line would obviate this rejection.

Claim Rejections - 35 USC §§ 102/103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1638

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 22, 23, 25, 31 and 33 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Harker *et al* (Canadian Journal of Plant Science, July 2000, 80(3):647-654).

Harker *et al* disclose the *Brassica napus* variety 45A71, one of the progenitors of Applicant's NS3213 line, having tolerance to at least one AHAS-inhibitor herbicide and comprising an AHAS 1 mutation and an AHAS 3 mutation (see page 648, right column).

Harker *et al* does not teach *Brassica* plants descendant from variety NS3213.

The instant plant are deemed *prima facie* obvious because one of ordinary skill in the art could not distinguish the progeny of variety NS3213 from progeny of variety 45A71 solely based on AHAS-inhibitor herbicide tolerance, especially given the fact that variety NS3213 has inherited its herbicide tolerance from variety 45A71. One of ordinary skill in the art would have had a reasonable expectation of success in making AHAS-inhibitor herbicide tolerant progeny using variety 45A71. Harker *et al* teaches that significant incentives remain for the development of HTC (herbicide tolerant canola), motivating one of ordinary skill in the art at the time of Applicant's invention to use variety 45A71 to make progeny plants comprising AHAS-inhibitor herbicide

Art Unit: 1638

tolerance. As stated above, over an undetermined number of generations, the identifying characteristics of each generation become highly varied, and since neither the individual traits themselves, nor their degree of expression, appear to be unique to the *Brassica* line NS2313, in particular having resistance to at least one AHAS-inhibitor herbicide, both characteristics known to be associated with other *Brassica napus* plants especially variety 45A71 and its progeny.

Claim Rejections - 35 USC § 103

13. Claims 24, 26, 32 and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Harker *et al* (Canadian Journal of Plant Science, July 2000, 80(3):647-654).

The teachings of Harker *et al* are outlined supra.

Harker *et al* does not teach crossing *Brassica napus* variety 45A71 with either *Brassica juncea* or *Brassica rapa* to make AHAS-inhibitor herbicide tolerant descendant *Brassica* plants.

Given the knowledge of one of ordinary skill in the art at the time of Applicant's invention, it would have been *prima facie* obvious to cross *Brassica napus* variety 45A71 with either *Brassica juncea* or *Brassica rapa* to make AHAS-inhibitor herbicide tolerant descendant *Brassica* plants. In addition, given the fact that *Brassica juncea* and *Brassica rapa* comprise the A genome, one of ordinary skill in the art would have had a reasonable expectation of success in making such a hybrid *Brassica* plant having at least partial tolerance to at least one AHAS-inhibitor herbicide as the result of

Art Unit: 1638

inheritance of either the AHAS1 mutation or the AHAS3 mutation present in *Brassica napus* variety 45A71.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 22-26 and 31-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 14-19 of copending Application No. 09/994,092. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed *Brassica* plant or *Brassica juncea* plant of the instant specification would be considered obvious in view of the claimed plant cell or plant having resistance to at least one AHAS-inhibitor herbicide in the copending application. The NS3801 *Brassica napus* variety is taught as having at least one AHAS-inhibitor herbicide resistance and was developed using variety 45A71, a common progenitor plant as the exemplified NS3231 variety of the instant application, and thus meet the limitations of the instant claims (see page 12 of the copending application). Said copending application also teaches

crossing the exemplified NS3801 variety with *Brassica juncea* in method of breeding well known to one of ordinary skill in the art at the time of Applicant's invention (see page 10 of the copending application).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Claims 27-30 are free of the prior art, which neither teaches nor fairly suggests a *Brassica juncea* plant having full tolerance to at least one AHAS-inhibitor herbicide and wherein both the AHAS1 mutation and the AHAS3 mutation are present.

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
9 January 2004

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600